

## **ViiV Healthcare Receives FDA approval for the HIV Integrase Inhibitor Tivicay<sup>®</sup> (dolutegravir)**

**Osaka, Japan, August 13, 2013** - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that the UK-based company, ViiV Healthcare Ltd. (Head Office: London; Chief Executive Officer: Dr. Dominique Limet) has issued a press release on August 12, 2013, BMT, regarding the approval of the HIV integrase inhibitor, Tivicay<sup>®</sup> (generic name: dolutegravir) by the United States Food and Drug Administration (FDA).

Tivicay<sup>®</sup> is an integrase inhibitor for the treatment of patients with HIV infection, which had been developed by Shionogi-ViiV Healthcare LLC (Shionogi’s compound code: S-349572), and subsequently by ViiV Healthcare following the new agreement between Shionogi and ViiV Healthcare which was announced in October, 2012. ViiV Healthcare filed a New Drug Application for Tivicay<sup>®</sup> in the US, EU and Canada on December 17, 2012. The FDA granted priority review and the target date for the completion of the review under the Prescription Drug User Fee Act (PDUFA) was August 17, 2013. FDA approved Tivicay<sup>®</sup> on August 12’.

With the approval, Tivicay<sup>®</sup> is now available as an innovative treatment option for people living with HIV in the US. Shionogi is very pleased that this milestone has been achieved and will continue to work to maximize the value of Tivicay<sup>®</sup> and the other integrase inhibitor assets of ViiV Healthcare as a shareholder.

### **Forward-looking Statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

### **For further information, contact:**

Corporate Communications

Shionogi & Co., Ltd.

Osaka Telephone: +81-6-6209-7885 Fax: +81-6-6229-9596

Tokyo Telephone: +81-3-3406-8164 Fax: +81-3-3406-8099